

REMARKS/ARGUMENTS

Claims 1, 4-6, 8-11, and 14 are pending. No claims have been added, amended, or canceled.

Applicants would like to thank the examiner for reconsidering and withdrawing the 35 U.S.C. § 102, § 112, second paragraph, and double patenting rejections. All claims, however, stand rejected as allegedly exceeding the scope of enablement. Applicants respectfully assert that the claims are fully enabled by the specification. As such, Applicants traverse the rejection.

The Federal Circuit has consistently held that “the specification must teach those of ordinary skill in the art how to make and use the full scope of the invention without undue experimentation.” *In re Wright*, 999 F.2d 1557,1561 (Fed. Cir. 1993). The specification need not explicitly teach those in the art to make and use the invention; the requirement is satisfied if, given what they already know, the specification teaches those skilled in the art enough that they can make and use the invention without “undue experimentation.” *Amgen*, 314 F.3d at 1334. The fact that a quantity of experimentation, even complex experimentation, may be required is not dispositive of the analysis (MPEP 2164.04). The key word is “undue,” not “experimentation”. *In re Angstadt*, 537 F.2d 498,504 (CCPA 1976). The factors to be considered in determining whether experimentation is undue include the breadth of the claims; the nature of the invention; the state of the prior art; the level of one of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples; and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). It is improper to conclude that a disclosure is not enabling based on analysis of only one of the factors while ignoring one or more of the others. MPEP 2164.01(a).

Nevertheless, not everything necessary to practice the invention need be disclosed. The Federal Circuit has stated that what is well-known is best omitted. *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991). Further, the scope of enablement must only bear a reasonable connection to the scope of the claims. See, e.g., *In re Fisher*, 427 F.2d 833, 839 (CCPA

DOCKET NO.: CELL-0145
Application No.: 09/964,161
Office Action Dated: November 13, 2003

PATENT

1970). Additionally, as the Federal Circuit recently reiterated, the law is clear that the specification need teach only one mode of making and using a claimed composition. *Amgen*, 314 F.3d at 1335.

In the instant application, the Office Action acknowledges that the specification is enabling for compositions where "Het" is a monocyclic system (page 2 of the Office Action). The Office Action, however, alleges that the specification does not enable one skilled in the art to prepare compounds where "Het" is a substituted 9- to 13-membered fused ring (pages 2-3 of the Office Action). The basis for this allegation appears to be the Office's belief that the specification does not show any examples related to 9- to 13-membered fused ring compounds (page 3 of the Office Action). Applicants respectfully disagree with this assessment. Example 5(d) on page 48, ll 15-22, for example, concerns a compound where "Het" is 1-methyl-2-indolyl. In Example 5(j) on page 49, ll 30-35, "Het" is quinoline-4-yl. Both of these examples are directed to 9- to 13-membered fused ring systems and serve as typical examples of "Het" moieties. Furthermore, the starting materials for these examples, 1-methylindole-2-carboxylic acid and 4-quinolinecarboxylic acid, are easily obtainable from Aldrich Chemical Company (Milwaukee, WI). One skilled in the art would be able to prepare other compounds with a 9- to 13-membered heterocyclic ring based on the disclosure described above without undue experimentation. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

DOCKET NO.: CELL-0145

Application No.: 09/964,161

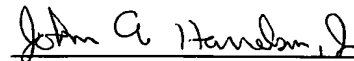
Office Action Dated: November 13, 2003

PATENT

It is believed all of the claims presently before the Examiner patentably define the invention over the prior art and are otherwise in condition for ready allowance. An early Office Action to that effect is, therefore, earnestly solicited.

Respectfully submitted,

Date: 2/11/04



John A. Harrelson, Jr.

Registration No. 42,637

Woodcock Washburn LLP
One Liberty Place - 46th Floor
Philadelphia PA 19103
Telephone: (215) 568-3100
Facsimile: (215) 568-3439